K102705

DEC - 7 2010

510(k) Summary

The 510(k) Summary is submitted in accordance with 21 CFR §807.92 and the requirements of the Safe Medical Device Act (SMDA) of 1990.

Submitter's Name	Abbott Vascular
Submitter's Address	3200 Lakeside Drive, Santa Clara, CA 95054
Telephone	(408) 845-0688
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Contact Person	Laarni Ricafort
Date Prepared	September 14, 2010
Device Trade Name	Armada 14 PTA Catheter
Device Common Name	PTA Catheter
Device Classification Name	Catheter, angioplasty, peripheral, transluminal
Predicate Device Names	VIATRAC 14 PLUS Peripheral Dilatation Catheter (K072798, cleared 01/21/08)
	Amphirion Deep 0.014 OTW PTA Balloon Catheter (K050073 cleared 2/11/05, K052791 cleared 11/04/05, and K083919, cleared 03/13/09)

Device Description

The Armada 14 PTA Catheter is a standard over-the-wire (OTW) balloon catheter to be used for percutaneous transluminal angioplasty (PTA). It is available in balloon lengths of 20 mm to 200 mm, with nominal diameters of 1.5 mm to 4.0 mm. The balloon has a nominal diameter inflation pressure of 8 atm and a rated burst pressure of 14 atm. Two polymer marker bands mark the working length of the balloons. The catheter shaft has working lengths of 90 and 150 cm. The inner lumen will accept a 0.014" guide wire. The outer shaft has a polycarbonate y-arm luer adhesively bonded to the proximal end to allow for entry to the guide wire lumen and to allow for connection of the inflation device to the inflation/deflation lumen.

Indication for Use

The device is indicated to dilate stenoses in femoral, popliteal, infra popliteal and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. The 2.0 to 4.0 mm balloon diameters are also indicated for post-dilatation of balloon-expandable stents up to 40 mm and self-expanding stents up to 80 mm in the vessels listed above.

Technological Characteristics

Comparisons to the predicate devices show that the technological characteristics such as product performance, design and intended use are substantially equivalent to the current marketed predicate devices.

Performance Data

Performance testing was successfully completed on the Armada 14 PTA Catheter. The following tests were conducted:

- Simulated Use (Pushability)
- Balloon Compliance
- Delivery System Dimensions
- Balloon Dimensions
- Catheter Bond Tensile Testing
- Pullback Force into Sheath
- Balloon Inflation/Deflation Time
- Catheter Body Burst Pressure
- Guide Wire Lumen Collapse
- Balloon Preparation and Flexibility and Kink Test
- Torque Strength
- Minimum Balloon Burst Strength (RBP)
- Balloon Fatigue (Repeat Balloon Inflations)
- Minimum Balloon Burst Strength in Stent
- Balloon Fatigue (Repeated Inflations) in Stent
- Biocompatibility
  - Cytotoxicity – Qualitative (L929 MEM Elution Test- ISO)
  - Irritation – Intracutaneous Irritation -- ISO
  - Sensitization study –Murine Local Lymph Node Assay -- ISO
  - Acute Systemic Toxicity -- ISO
  - Pyrogen – Study Material Mediated -- ISO
  - Hemocompatibility Investigations – Direct Method
  - Hemocompatibility Investigations – Indirect method study
  - Complement Activation (C3a & SC5b9)
- Packaging and Sterilization Validation
- Shelf Life (Accelerated Aging)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Abbott Vascular
c/o Laarni Ricafort
Regulatory Affairs Associate
3200 Lakeside Drive
Santa Clara, CA 95054

DEC - 7 2010

Re: K102705
Trade/Device Name: Armada 14 PTA Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: LIT, DQY
Dated: September 17, 2010
Received: September 20, 2010

Dear Ms. Ricafort:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. However, we remind you that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE STATEMENT

510(k) Number (if known): K102705

Device Names: Armada 14 PTA Catheter

Indications for Use: The device is indicated to dilate stenoses in femoral, popliteal, infra popliteal and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. The 2.0 to 4.0 mm balloon diameters are also indicated for post-dilatation of balloon-expandable stents up to 40 mm and self-expanding stents up to 80 mm in the vessels listed above.

Prescription Use__X__ OR Over-The-Counter_____
(Per 21 CFR 801.109) (Optional Format 1-1-96)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K102705